

PENDING CLAIMS

1. (Original) A method for forming a proximal anastomosis of a graft vessel on a fluid-carrying vessel in a patient's body, the method comprising:
  - forming an aperture in a wall of the vessel;
  - introducing through the aperture and into the vessel in confined configuration a resilient, flexible sealing element having a central stem and having a continuous disassociation region formed thereon to extend from the central stem;
  - expanding the sealing element to peripheral dimensions greater than the dimension of the aperture;
  - retaining the sealing element in position covering the aperture in sealing engagement within the vessel;
  - substantially completing anastomosing the graft vessel on the fluid-carrying vessel over the aperture, retaining an incomplete segment overlapping the central stem for removal of the sealing element;
  - disassembling the expanded sealing element along the disassociation region extending from the central stem for removal thereof as a continuous strand through the incomplete segment; and
  - completing the anastomosis of the graft vessel on the fluid-carrying vessel including along the incomplete segment.

2. (Original) The method according to claim 1 in which forming an aperture includes augering into a wall of the fluid-carrying vessel in relation to a cutting edge for cutting tissue in the vessel wall to form the aperture and retaining the tissue cut therefrom.

3. (Original) The method according to claim 1 in which a resilient retainer is positioned on an outer wall of the vessel near the aperture for supporting a filament thereon in tension that is attached to the sealing element through the aperture to retain the sealing element in the sealing engagement with an inner wall of the fluid-carrying vessel.

4. (Original) The method according to claim 1 in which substantially completing anastomosing the graft vessel includes forming suture attachment thereof to the fluid-carrying vessel about the perimeter of the aperture, with the central stem of the sealing element extending through the anastomosis near the last suture attachment;

disassembling the sealing element along the disassociation region thereof for withdrawal as a single continuous strand through the incomplete segment of the anastomosis; and

completing the anastomosis following removal of the sealing element.

5. (Original) The method according to claim 4 in which disassembling the sealing element includes introducing an elongated tube over the central stem and through the incomplete segment of the anastomosis; and

exerting tensile force on the central stem relative to the elongated tube to pull therethrough the central and subsequent portions of the sealing element as disassembled into a single continuous strand along the disassociation region.

6. (Original) The method according to claim 1 in which the disassociation region extends along a spiral path between the central stem and perimeter of the sealing element.

7. (Withdrawn) A method for forming a sealing element for insertion and removal with respect to a fluid-carrying vessel of a patient, the method comprising:

forming fluid-impervious flange extending radially from a central region to a substantially circular periphery; and including

forming a continuous disassociation region along a meandering path from the central region to the circular periphery.

8. (Withdrawn) The method according to claim 7 including forming a central stem on the flange and integral therewith along the continuous dissociation region.

9. (Withdrawn) The method according to claim 7 including forming an attachment structure near a proximal end of the stem for exerting tensile force thereon.

10. (Withdrawn) The method according to claim 7 in which the flange is formed as a continuously-wound spiral of thermoplastic material having contiguous lateral edges along adjacent convolutes; and selectively heating and pressing together the lateral edges of contiguous convolutes to lightly adhere the convolutes to form the fluid-impervious flange of the sealing element.

11. (Withdrawn) The method according to claim 7 in which the flange is formed with a continuous disassociation pattern of reduced thickness of the flange from a central region thereof to the periphery thereof for promoting disassembly of the flange along the disassociation pattern into a continuous strand from the central region to the periphery of the flange in response to force applied at the central region in relation to the flange.

12. (Withdrawn) A method of forming a temporary fluid-impervious sealing element comprising:

configuring a strand along a path and including an axial stem and a substantially lateral flange, with the path continuously meandering between the stem and an outer periphery of the flange; and

adhering contiguous adjacent segments of the strand in the stem and flange to form the fluid-impervious sealing element.

13. (Withdrawn) The method according to claim 12 in which the path substantially spirals between the stem and periphery of the flange with adjacent convolutes of the strand disposed in substantially contiguous array along the path.

14. (Withdrawn) The method according to claim 13 in which the strand includes thermoplastic material; and  
adhering includes applying heat and pressure at least to the flange to flow the material into fluid impervious attachments of contiguous adjacent convolutes of the strand.

15. (Withdrawn) A method for establishing a temporary fluid-tight seal within an aperture in a wall of a fluid-carrying vessel in the body of a patient, the method comprising:

introducing through the aperture a sealing element having a flange of substantially circular periphery and stem substantially normal to the flange in a central region thereof; and

exerting a supporting force through the aperture on one of the stem and flange for retaining fluid-sealing engagement of the circular periphery of the flange against an inner wall of the vessel covering the aperture.

16. (Withdrawn) The method according to claim 15 in which the flange of the sealing element includes substantially convex shape intruding into the vessel with the circular periphery thereof disposed about the aperture.

17. (Withdrawn) The method according to claim 15 in which a resilient member is disposed on an outer wall of the vessel and in which a tether is disposed in tension on the resilient member and extends through the aperture for attachment with the one of the stem and flange to exert the supporting force thereon.

18. (Withdrawn) A temporary sealing element for forming a fluid-tight seal on the inner wall of a fluid conduit within a patient's body, the temporary sealing element comprising:

a fluid impervious flange having an outer stem centrally formed thereon, the flange including a continuous region of diminished shear strength extending from

the stem along a continuous path to the periphery for selectively reconfiguring the flange in response to tension applied to the stem to disassemble the flange along the continuous region into a continuous strand.

19. (Withdrawn) The temporary sealing element according to claim 18 including a length of flexible, resilient material integrally forming the stem, and being helically wound to form successive convolutes outwardly from the stem to the periphery, with each convolute adhering to adjacent convolutes along lateral edges thereof to form the continuous region in the substantially fluid-impervious flange.

20. (Withdrawn) The temporary sealing element according to claim 19 in which the length of material includes a length of bioinert thermoplastic material forming the stem and flange and including thermoplastic adhesion between lateral edges of adjacent convolutes of the helically-wound length of material.

21. (Withdrawn) The temporary sealing element according to claim 19 in which the thermoplastic material is polyvinyl chloride.

22. (Withdrawn) The temporary sealing element according to claim 19 including an attachment structure at an end of the stem remote from the flange for selective engagement therewith to exert tensile force thereon.

23. (Withdrawn) The temporary sealing element according to claim 19 including a support structure attached to one of the stem and flange and including a resilient member disposed to expand from a confined configuration of smaller lateral dimension than the periphery of the flange to an expanded configuration of larger lateral dimension than the periphery of the flange.

24. (Withdrawn) The temporary sealing element according to claim 23 in which the resilient member extends laterally and includes a pair of mating ends disposed to traverse the periphery of the flange; and

a strand attached to the mating ends and to one of the stem and flange for supporting the stem and flange intermediate the mating ends of the resilient member.

25. (Withdrawn) The temporary sealing element according to claim 24 in which the resilient member includes a pair of arms extending to and including the mating ends and resiliently biased for outward extension of the mating ends.

26. (Withdrawn) The temporary sealing element according to claim 18 in which the flange is formed of flexible resilient material and includes a generally circular periphery and the stem integrally formed therewith; and in



which the region of diminished shear strength extends from the stem along a substantially helical path to the periphery.

27. (Withdrawn) A seal removal instrument for the temporary sealing element of claim 22 including an elongated hollow tube having a lumen therethrough between distal and proximal ends dimensioned to pass the stem and attachment structure therethrough;

an inner core slidably disposed within the tube and including an attachment structure at a distal end thereof to mate with the attachment structure at the end of the stem for exerting tensile force thereon;

said tube being positionable about the stem with the distal end of the tube disposed adjacent the flange and with the attachment structures of the inner core and stem engaged to exert tensile force on the inner core relative to the tube for extracting the stem and flange through the outer tube as the continuous strand.

28. (Withdrawn) The seal removal instrument of claim 27 in which the attachment structure on the stem includes a loop, and the attachment structure on the inner core includes a hook for engaging the loop.

29. (Withdrawn) A punch for forming an aperture in the wall of the fluid-carrying vessel in a patient's body, the punch comprising:

an elongated hemostatic sheath including a lumen therethrough between distal and proximal ends thereof;

a plunger element slidably and rotatably disposed within the lumen through the hemostatic sheath and carrying a tissue-penetrating member for selective axial extension thereof beyond the distal end of the hemostatic sheath to penetrate the wall of a fluid-carrying vessel.

30. (Withdrawn) A punch according to claim 29 in which the tissue-penetrating member includes a corkscrew-style tissue penetrator and includes a substantially circular cutting edge in close proximity thereto mounted for relative rotational motion therebetween.

31. (Withdrawn) A punch accordingly to claim 29 including a valve disposed in the hemostatic sheath for inhibiting outflow of fluid therethrough.

32. (Withdrawn) A punch according to claim 30 in which the distal end of the hemostatic sheath forms the cutting edge in close proximity to the tissue penetrator.

33. (Withdrawn) A kit of surgical components for anastomosing a graft vessel on a fluid-carrying vessel, comprising:

a punch for forming an aperture in a fluid-carrying vessel;

a sealing element including a continuous strand of material extending along a path forming an axial stem and a substantially lateral flange to a perimeter thereof of dimension greater than an aperture formable by the punch; and an insertion instrument incorporating the sealing element in configuration for positioning the sealing element within an aperture formable by the punch.

34. (Withdrawn) The kit according to claim 33 including an extraction instrument having a lumen extending therethrough of sufficient dimension between proximal and distal ends thereof for passing the strand of material therethrough.

35. (Withdrawn) The kit according to claim 33 including a resilient frame disposed about the sealing element and including a flexible tether that is tensioned by the frame and that engages the sealing element in a combined structure of sealing element supported by the tether on the resilient frame.

36. (Withdrawn) The kit according to claim 35 in which the insertion instrument includes an elongated hollow tube having proximal and distal ends, with the combined structure confined within the hollow tube near the distal end thereof in compressed configuration for selective deployment therefrom to a configuration that tensions the tether for supporting the sealing element on the resilient frame.

37. (Withdrawn) The kit according to claim 33 including an envelope surrounding the punch and sealing element and insertion instrument for maintaining a sterile environment thereabout.

38. (Withdrawn) A method for preparing for insertion into a vessel an anastomotic seal having a resilient fluid-impervious flange and a stem attached thereto and having a resilient member including a pair of mating ends tethered by a strand attached in tension therebetween and attached to one of the flange and stem, the method comprising:

confining the resilient member within a tube with the mating ends in substantially contiguous orientation with the strand therebetween untensioned; and

confining the flange and stem within the tube in substantially tandem orientation relative to the resilient member.

39. (Withdrawn) The method according to claim 38 in which the flange confined within the tube is rolled laterally across a diameter thereof, with the stem oriented in substantial alignment with the roll axis of the flange.

40. (Withdrawn) The method according to claim 38 including a plunger axially slidable within the tube and comprising:

orienting the plunger at a position within the tube remote from distal end thereof in tandem proximity to the resilient member, with the flange of the seal

disposed near the distal end of the tube.

41. (Withdrawn) The method according to claim 40 including sliding the plunger axially within the tube toward the distal end thereof to eject from the tube at least the flange and stem of the seal, the resilient member tethered to the seal between mating ends thereof being selectively retrieved from the tube to resiliently expand and tension the strand.

42. (Withdrawn) Apparatus for forming a temporary seal within a blood vessel, comprising:

a tube having a bore therein and including a plunger axially slidable within the bore;

a fluid-impervious flange of resilient material disposed within the bore near a distal end thereof, the flange having a stem extending substantially normally therefrom and rolled laterally substantially about a diameter of the flange with the stem extending within the bore proximally from the distal end thereof;

a resilient member confined within the bore intermediate the flange and plunger, the resilient member including a pair of arms extending to mating ends for tensioning a strand attached thereto and to one of the flange and stem, the pair of arms being disposed within the bore in substantially contiguous orientation with the strand untensioned between the mating ends.

43. (Withdrawn) Apparatus according to claim 42 in which the pair of arms are resiliently extendable substantially about a pivot axis positioned within the bore adjacent the plunger with the mating ends disposed near the flange for deployment from the distal end of the bore of at least the flange and stem in response to axial movement of the plunger toward the distal end of the bore.